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08/486,066 06/07/95 ENGELHARDT

D ENZ (D5) (C2)

EXAMINER

MARSHALL, A

18M2/0625

ART UNIT

PAPER NUMBER

25

RONALD C FEDUS
ENZO DIAGNOSTICS INC
ENZO BIOCHEM INC
575 FIFTH AVENUE 18TH FLOOR
NEW YORK NY 10017

1807

DATE MAILED:

06/25/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

6-7-95 9-12-95
9-11-95 9-19-95
10-25-95 11-17-95
9-11-95

☒ This application has been examined ☒ Responsive to communication filed on 9-11-95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 238-297 and 299-307 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-237 and 298 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 238-297 and 299-307 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

08/486,066

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title, albeit thorough, is somewhat lengthy and a shortened version is hereby requested.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 238, 240-272, 274-297, and 299-307 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to "covalent" attachment of the Sig moiety to the sugar (SM) via the vicinal hydroxyls at the 2' or 3' position. It is noted that the only instantly disclosed chemistry for Sig attachment to the SM moiety is given on page 53, first full paragraph, via the formation of dialdehydes that are then coupled to biotin hydrazide. It is noted that another possible SM attachment of a Sig moiety is at the 2', 3', or 5' hydroxyls of SM via phosphorylation. This, however, occurs via phosphate group attachment. Therefore, the other embodiments of the instant disclosure would seem to be meant therefore because a phosphate group is involved. For example, if a labeled mononucleotide were attached to a 3' or 5' hydroxyl of a particular SM moiety this would seem to be a PM type attachment and not an SM attachment. In summary, the bases of nucleotides

are well known to contain reactive groups that are also well known to require protective groups to prevent undesired reactions when other portions of a nucleotide are being modified, with the single exception of the above mentioned phosphorylation or the periodate oxidation of vicinal 2'-3' hydroxyls. Therefore, any other chemistry for SM labeling with Sig is not apparent and thus undue experimentation. It is noted that claim 238, for example, is not limited as to the point of attachment of Sig to SM as well as not being limited as to a covalent character to said SM labeling and thus broader in scope compared to the apparently available SM labeling methods. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 238-297 and 299-307 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,260,433. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both sets of claims include the SM labeled nucleotide as well as polymers that are SM labeled with a Sig moiety of the same type but the claims are not the same in scope between the claim sets. It is noted that claim 20 of the patent is directed to a polynucleotide. It is additionally noted that applicants have previously submitted a terminal disclaimer regarding said patent but applicants are hereby informed that this was in the parent application to the instant application and does not apply to the instant application. Terminal disclaimers must specifically cite both the instant application in which they are effective as well as the patent/application which is the basis for the disclaimer.

Consideration of the file record indicates that Applicants have filed IDSs on 9/11/95 and 10/25/95. Unfortunately, the forms 1449 likely were filed therewith listing the citations for consideration are not presently in the file. In order for any references to be considered as possible prior art applicants are requested to resubmit the forms 1449 regarding these IDSs.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CMI Fax Center number is either (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Serial No. 08/486,066

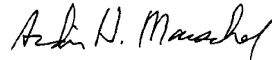
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Art Unit: 1807

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

June 24, 1996



ARDIN H. MARSCHEL
PATENT EXAMINER
GROUP 1800